



916-342-4133
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DEC - 5 1996

20 September 1996

K964243

510(k) SUMMARY

The 510(k) summary information required by CFR 807.92 is as follows:

- A. Classification name: Pin, fixation, smooth
Common/usual name: Fixation wire, fixation pin, nail, rod, and others
Proprietary name: Humerus Wires
- B. Substantial equivalence: Applied Osteo Systems True/Flex IM Rod System for the Humerus, Radius, and Ulna (K902264, K913949), Richards Ender Pins (K811002), O'Tec Corporation and Onyx Corporation Rush Pins (K905341 and K903261, respectively), and others.
- C. Device description: The Humerus Wires device is an internal wire fixation device to be used in the fixation of humeral fractures.
- D. Intended use: The Humerus Wires device is intended to be implanted in the humerus for internal fixation of fractures and/or reconstruction of the humeral bone.
- E. Technological characteristics: The Humerus Wires

device is similar to predicate devices in its design, function, and intended use.

The device is similar to certain predicates which do not utilize a locking screw, but it is unlike predicates which do utilize such a locking component.

The Humerus Wires device is manufactured from materials presently and/or previously utilized in FDA-cleared medical devices.

Submitted,

FERGUSON MEDICAL

FDA Establishment Registration Number 2937794

A handwritten signature in cursive script, appearing to read "Frank Ferguson", followed by a horizontal line.

Frank Ferguson

Official Correspondent